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Herrera et al.

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(54) **BLADDER MANAGEMENT SYSTEMS**

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A61F 2/00 (2006.01)
A61F 2/48 (2006.01)

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CPC ***A61F 2/0027*** (2013.01); ***A61F 2/0022*** (2013.01); *A61F 2002/48* (2013.01);
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See application file for complete search history.

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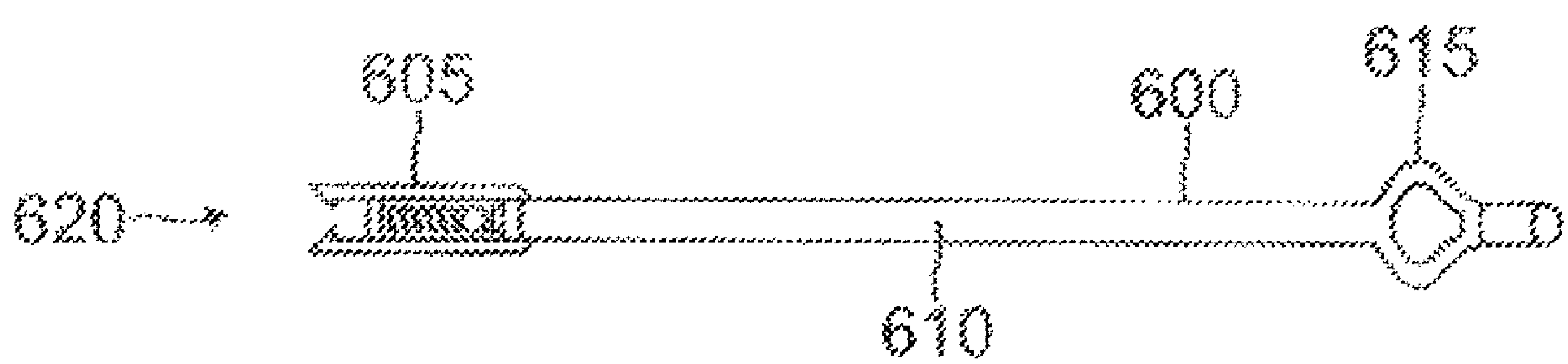
(57) **ABSTRACT**

The disclosure relates generally to an extended use systems and devices for management of bladder function for people with urinary dysfunction. The system includes a catheter which can include a sensor that can determine bladder condition and a valve that can control fluid flow. The catheter can be placed inside the bladder using devices that facilitate insertion and extraction. The placement of the catheter can be done by a trained individual such as a patient, as well as a clinician, a nurse, or a caretaker. Once placed inside the bladder, the catheter can be fully-internal, meaning no portion of the catheter is visible from outside of the patient's body.

14 Claims, 9 Drawing Sheets



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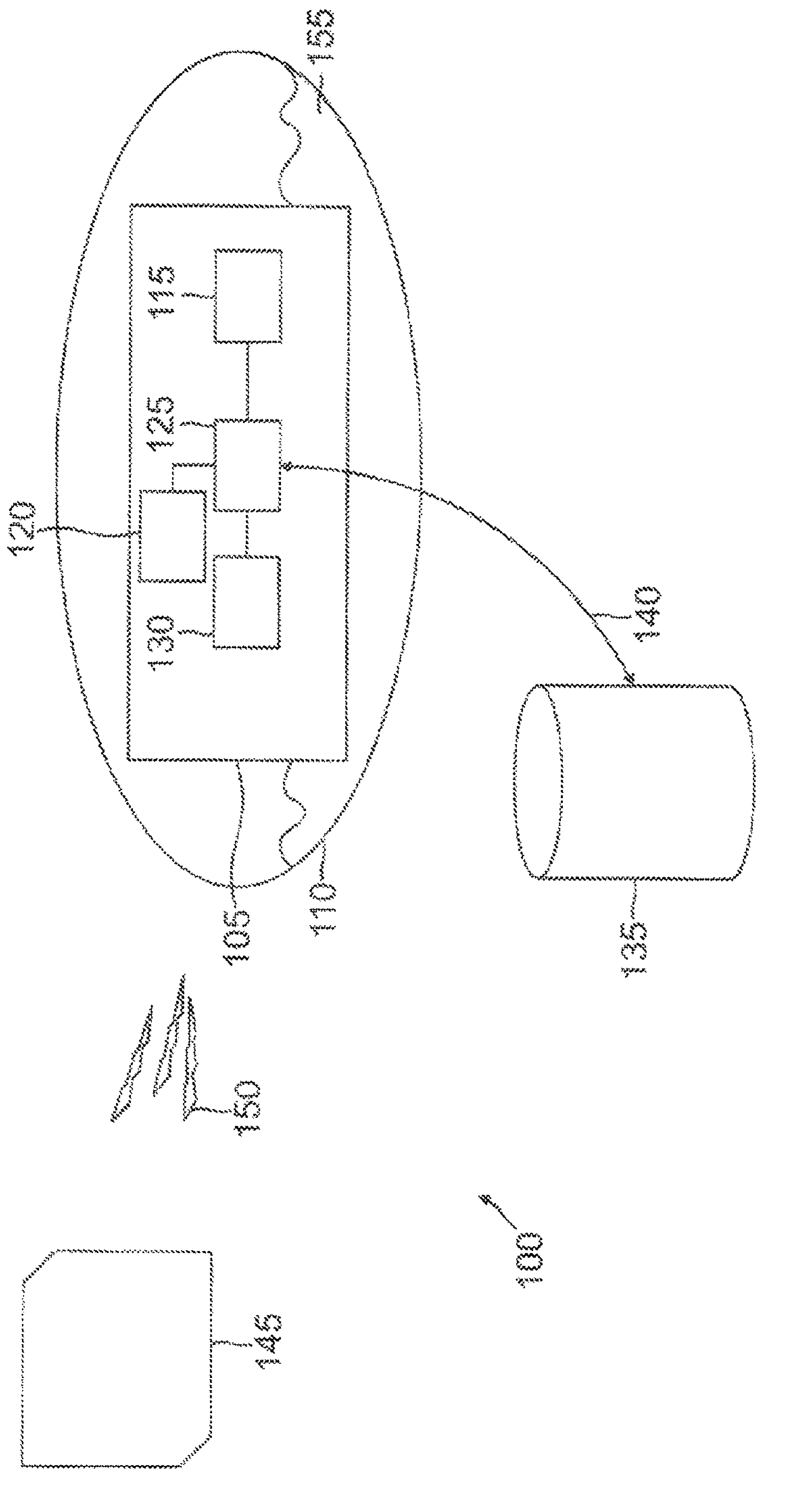

FIG. 1

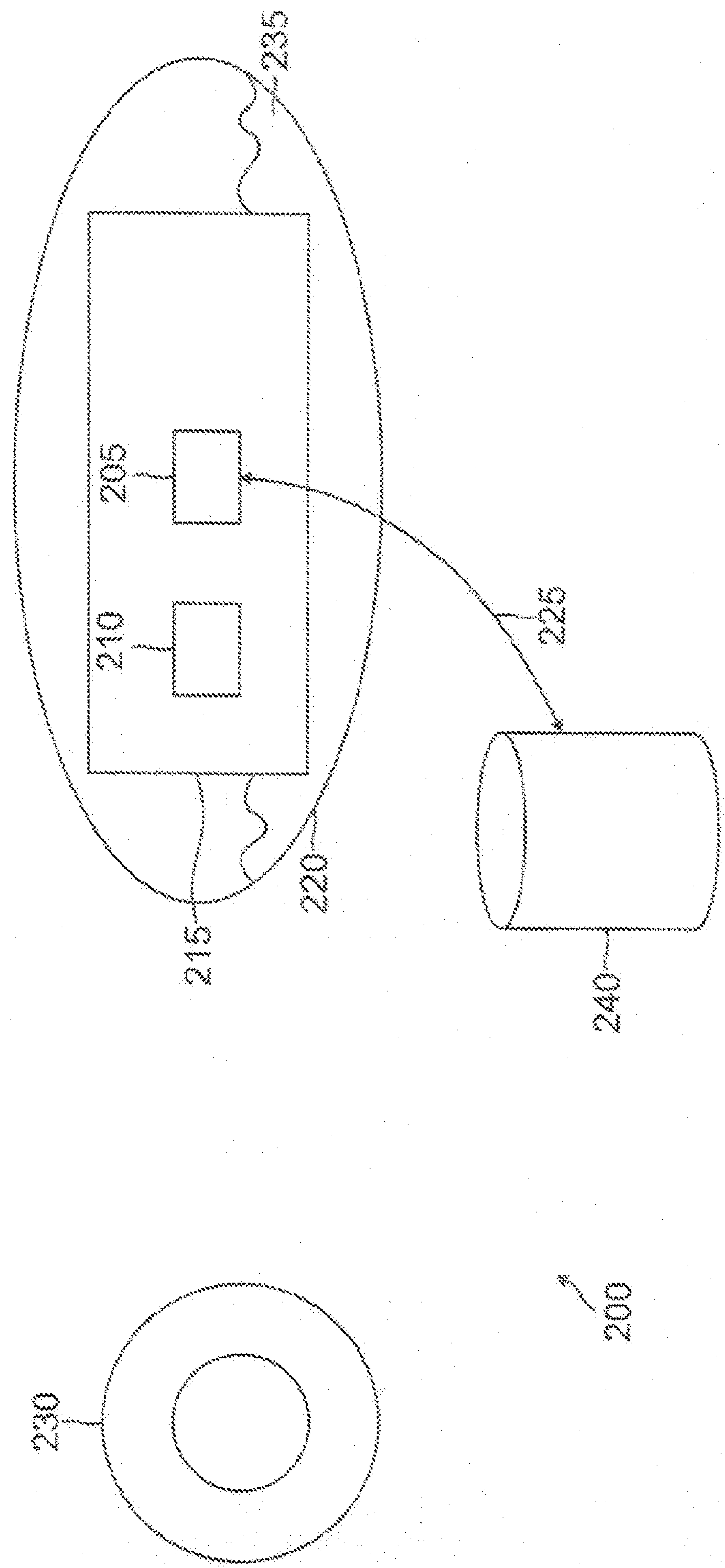

FIG. 2

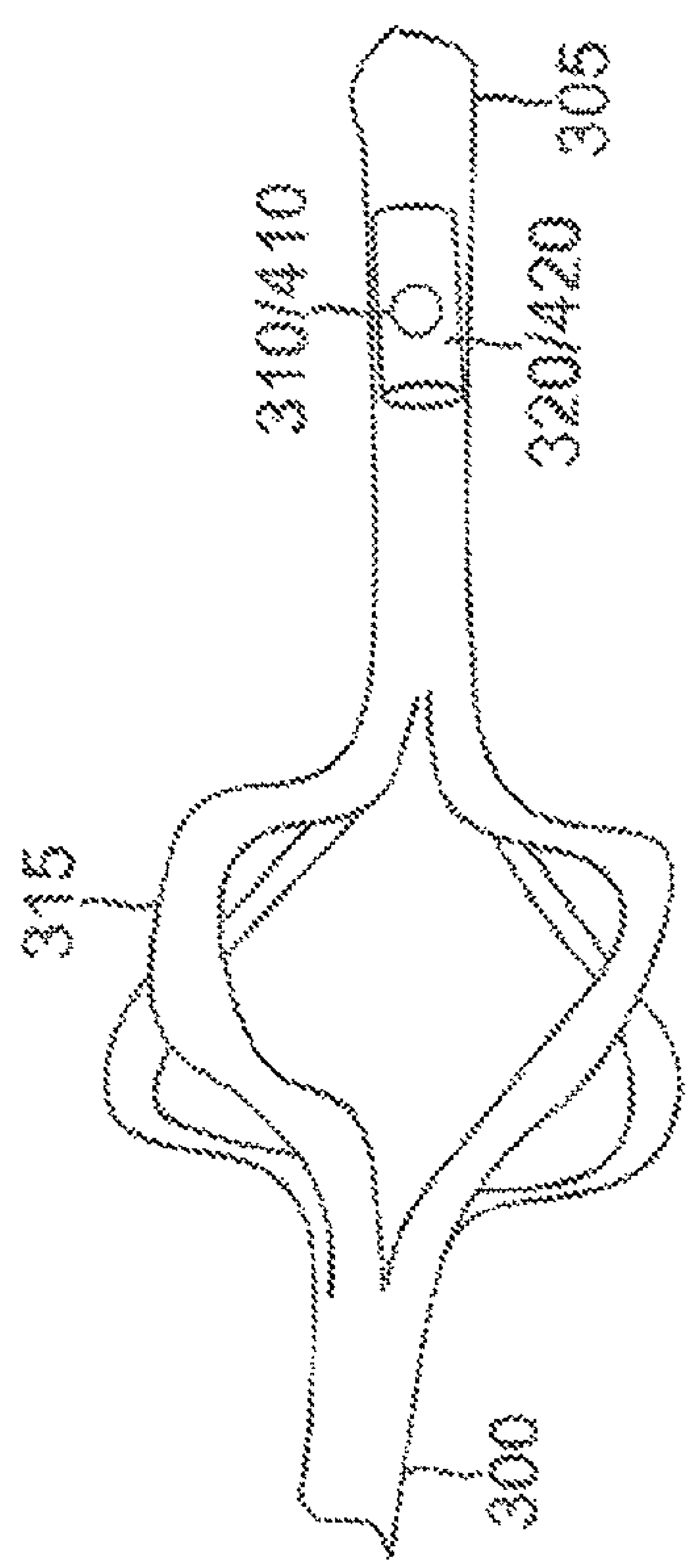

FIG. 3

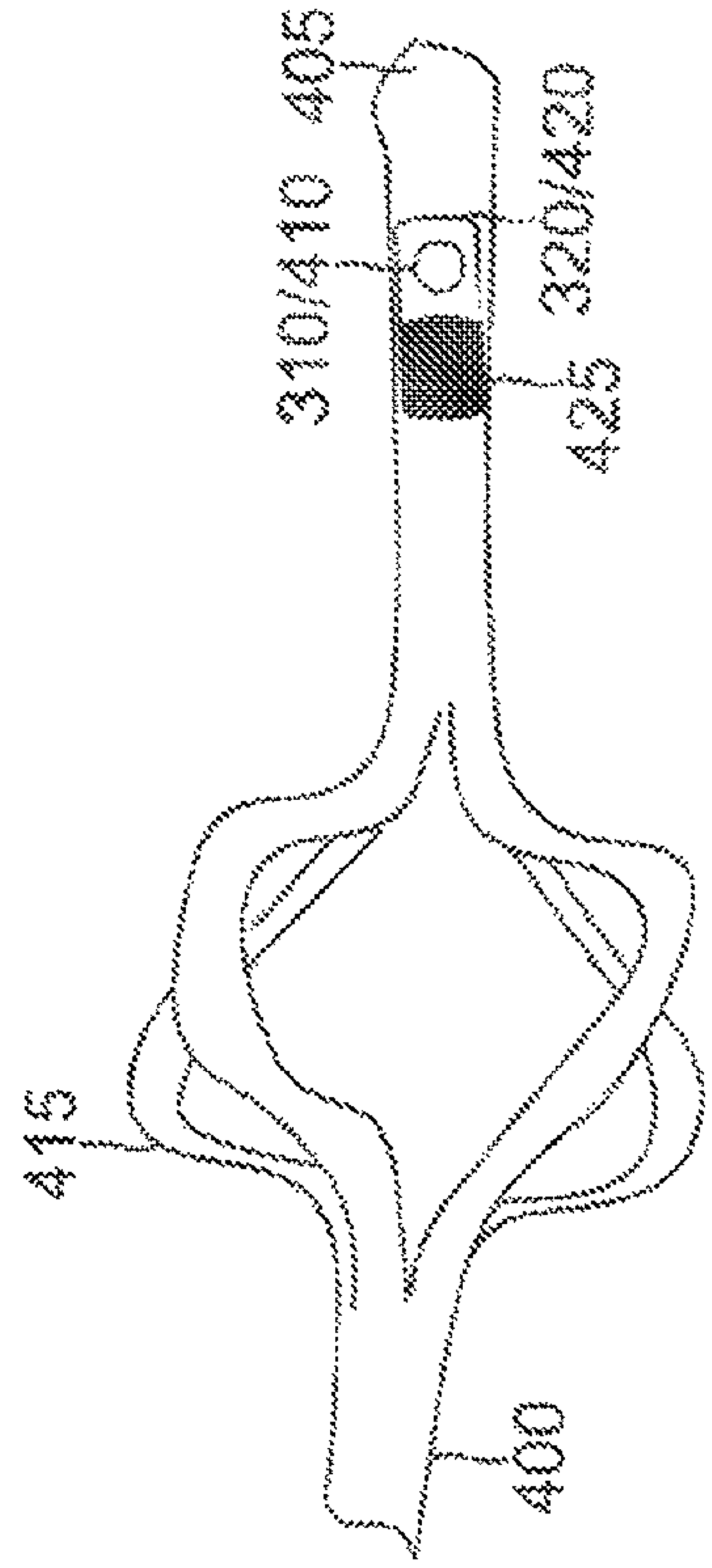

FIG. 4

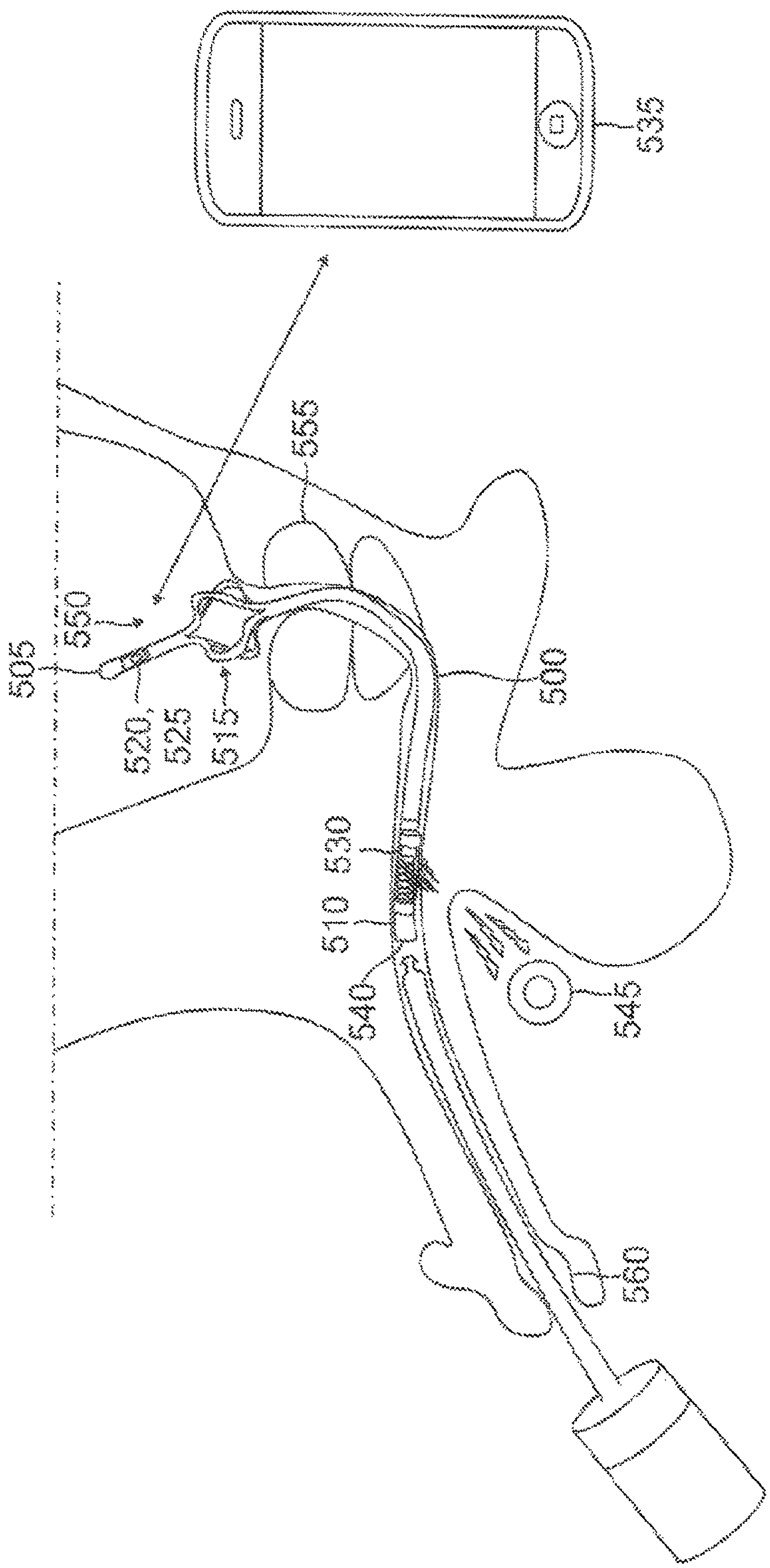

FIG. 5

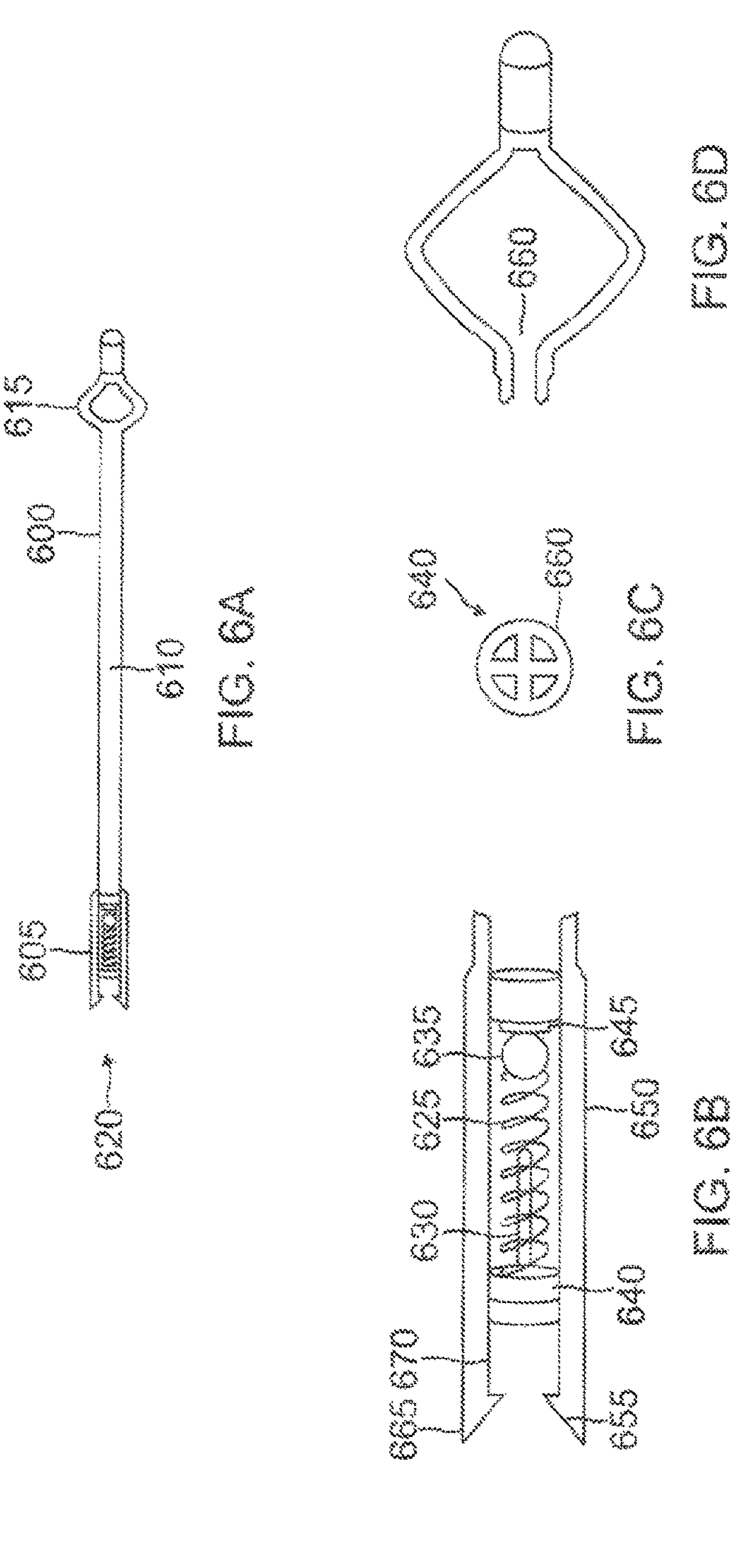

FIG. 6A

FIG. 6B

FIG. 6C

FIG. 6D

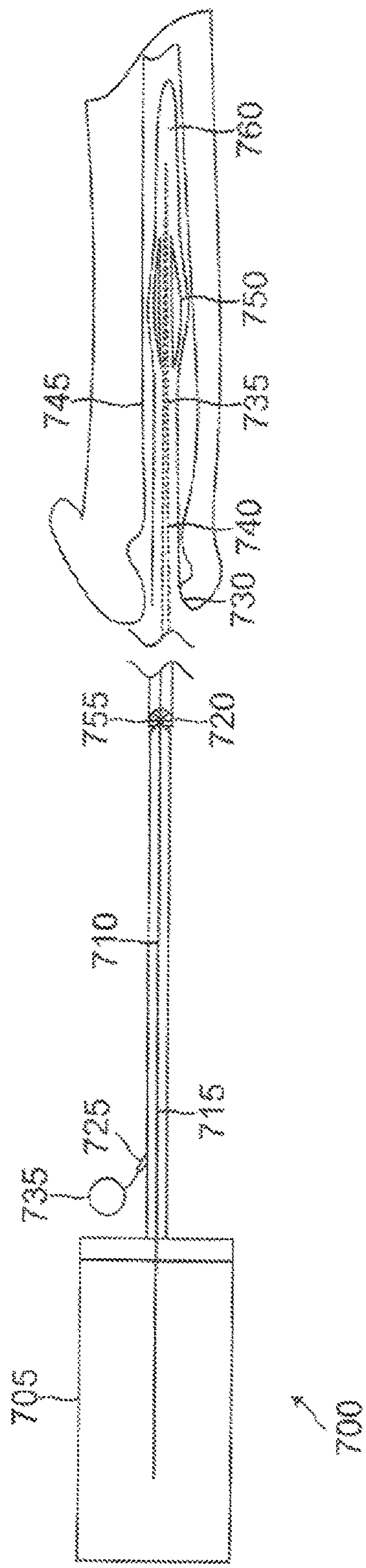

FIG. 7A

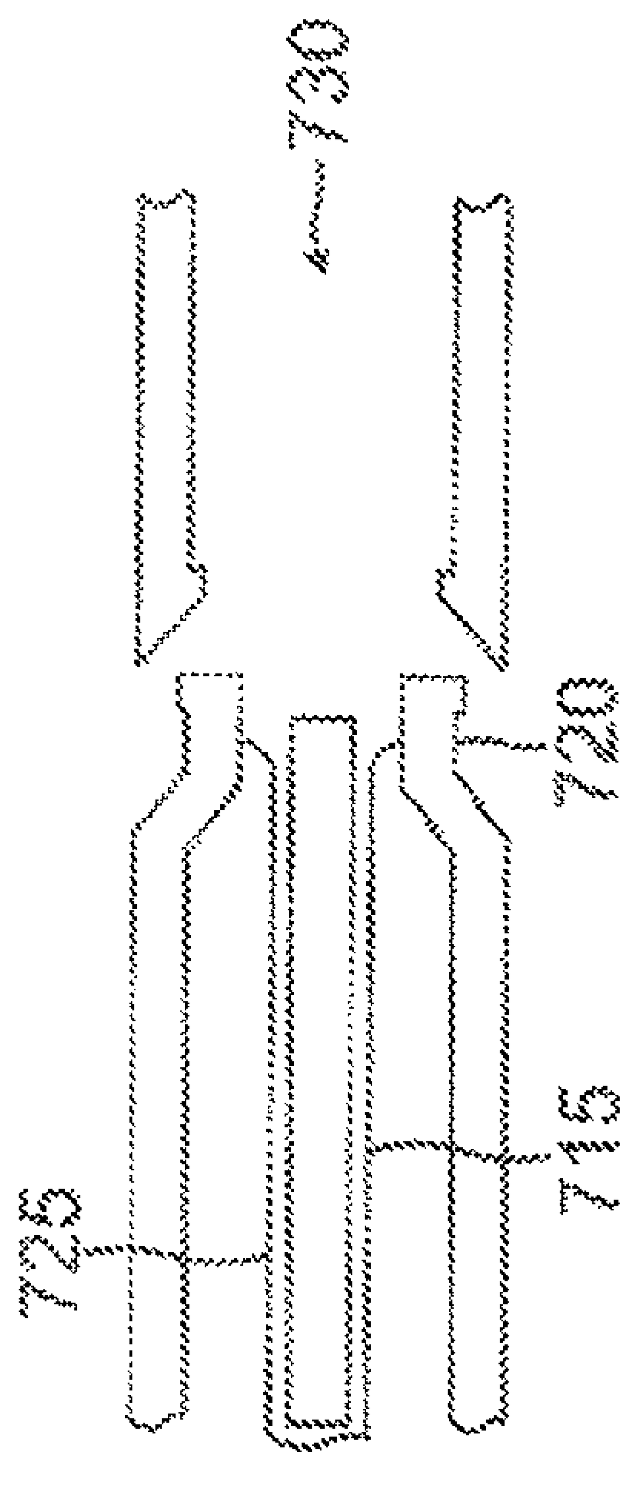

FIG. 7B

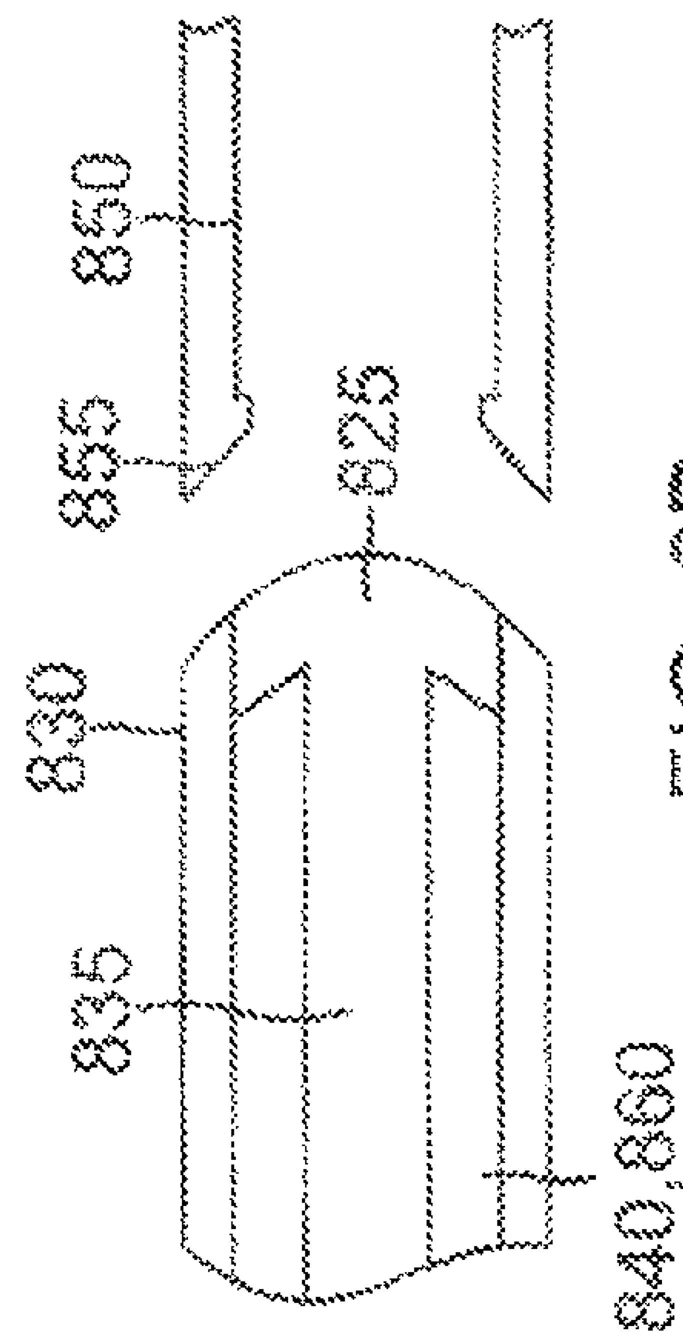

FIG. 8B

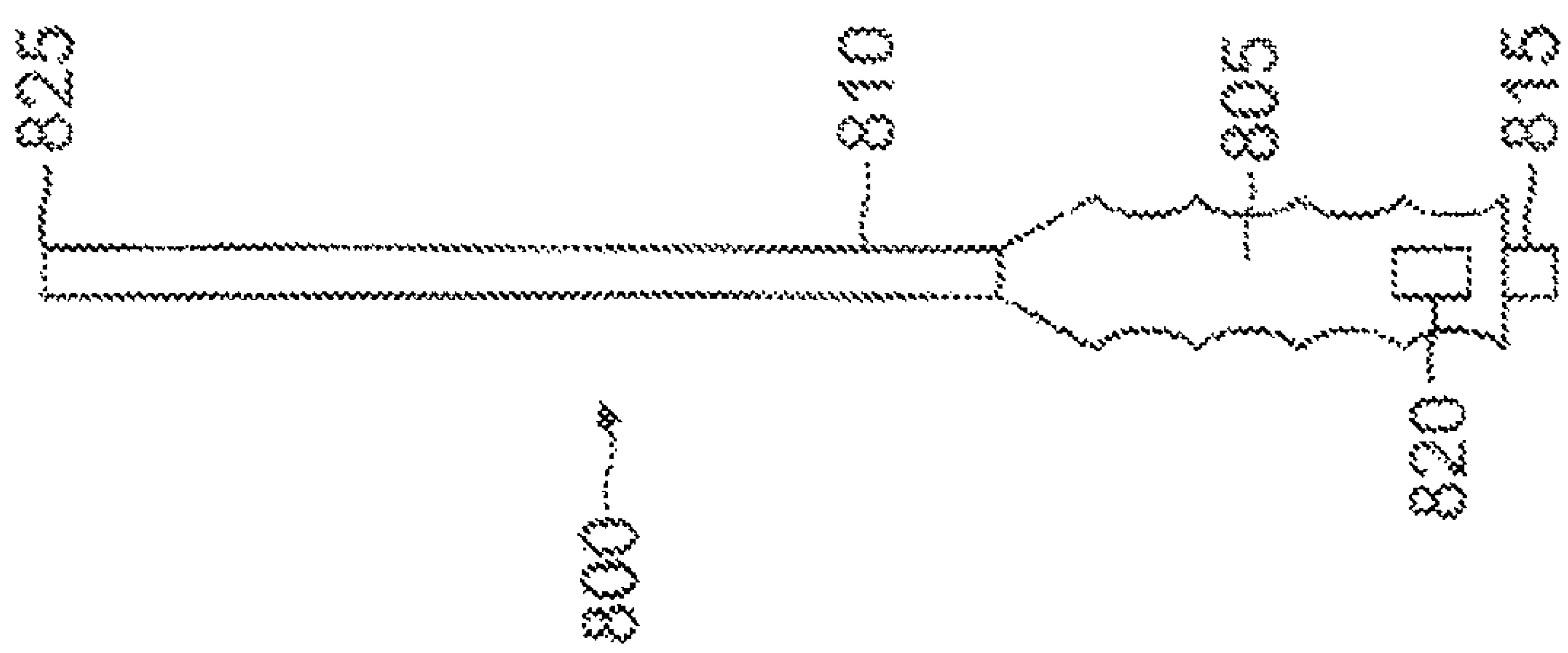

FIG. 8A

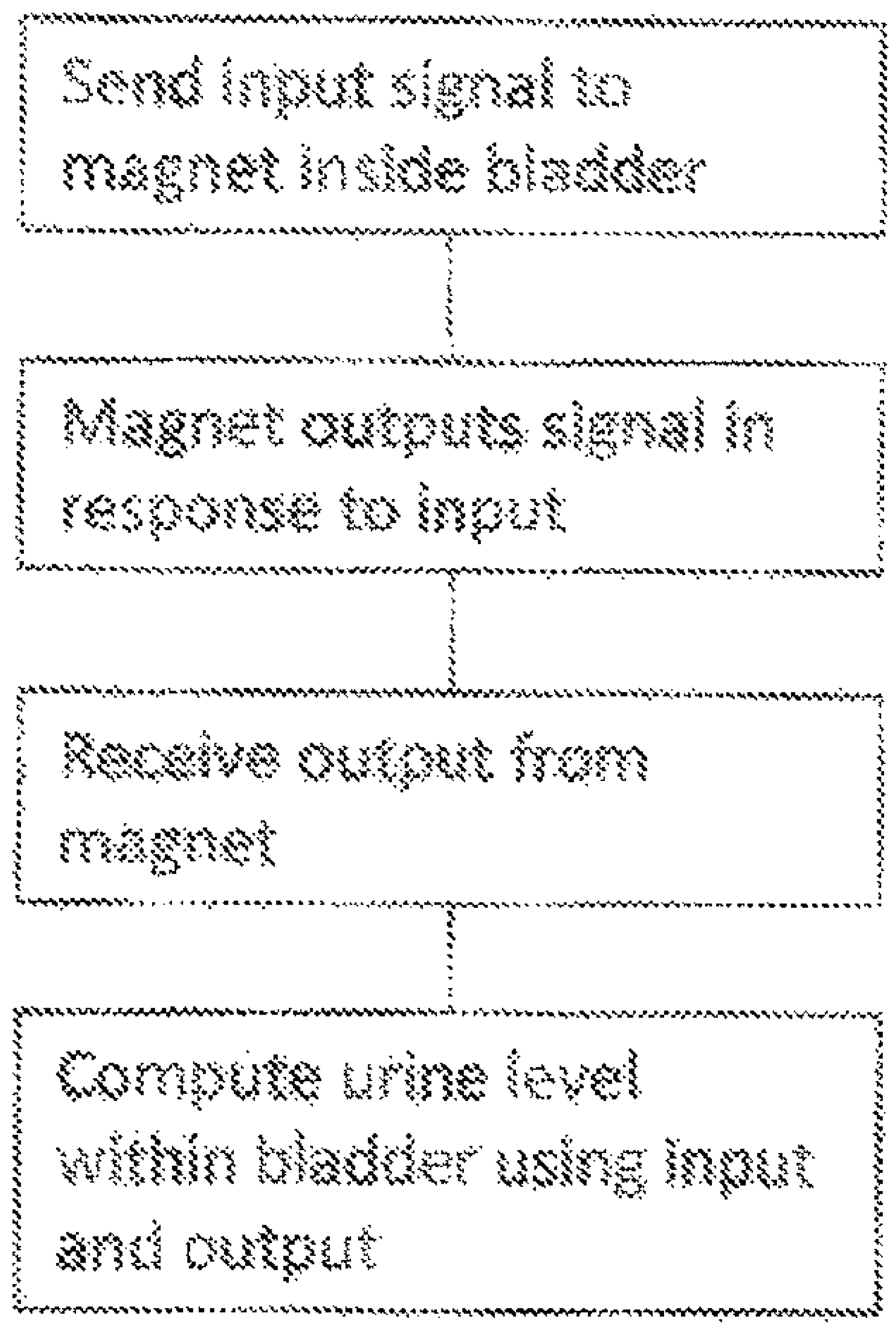
Send input signal to magnet inside bladder
Magnet outputs signal in response to input
Receive output from magnet
Compute urine level within bladder using input and output

FIG. 9

BLADDER MANAGEMENT SYSTEMS

CROSS REFERENCE TO RELATED APPLICATIONS

This application is a continuation of and claims priority to U.S. patent application Ser. No. 15/721,096, filed Sep. 29, 2017 which is divisional of and claims priority to U.S. patent application Ser. No. 15/419,948 (Now U.S. Pat. No. 9,775,698), filed Jan. 30, 2017 which is a continuation-in-part of, and claims priority to PCT Patent Application Serial No. PCT/US2016/014648, filed Jan. 23, 2016 which claims priority U.S. Provisional Application Ser. No. 62/107,203, filed Jan. 23, 2015, U.S. Provisional Application Ser. No. 62/141,520, filed Apr. 1, 2015, U.S. Provisional Application Ser. No. 62/231,854, filed Jul. 16, 2015, U.S. Provisional Application Ser. No. 62/275,671, filed Jan. 6, 2016, and U.S. Provisional Application Ser. No. 62/279,485, filed Jan. 15, 2016. Each of the foregoing applications are incorporated herein by reference in their entirety for all purposes.

FIELD

This disclosure generally relates to bladder management systems, and in particular, wireless sensors and urinary catheters.

BACKGROUND

Currently, there are a significant amount of people that suffer from bladder issues where they are unable to sense the amount of urine in their bladder and when they need to urinate. One condition resulting in this symptom is the Neurogenic Bladder, often found in individuals suffering from paralysis. Many of these individuals lack sensation below their levels of injury and this results in someone who is required to use intermittent catheters to allow urine to empty their bladder. Because they are unable to determine the exact amount of urine stored in their bladder, and unable to sense the fullness, they often utilize a time schedule to ensure they don't experience urinary accidents. This is very inefficient and increases the risk of Urinary Tract Infections, urethral damage due to False Passage, and other issues. If these individuals were able to decrease the number of times they are catheterized, it would improve the individual's comfort and decrease their risk of infection and other complications. A device that alerts them the amount of urine currently in their bladder can allow individuals to more accurately determine the timing to release the urine stored in their bladder instead of being required to utilize a time schedule. A valve device that is fully internal to the individual's body, which also allows the individual to open and close the valve from outside the body, would decrease the need to remove and replace the catheter while reducing the likelihood of foreign objects entering the urethra. It is, therefore, desirable to provide an improved sensor and valve on a catheter, that overcomes most, if not all, of the preceding problems.

SUMMARY

The present technology relates to systems and method for controlling the urinary system and, in particular, long-term use device for bladder management and awareness regarding bladder fullness.

BRIEF DESCRIPTION OF THE DRAWINGS

The following drawings and the associated descriptions are provided to illustrate the present disclosure and do not limit the scope of the claims.

FIG. **1** shows a generalized schematic drawing of a sample bladder management system.

FIG. **2** shows a generalized schematic drawing of a sample bladder management system using a signal generating sensor.

FIGS. **3** and **4** schematically show different embodiments of sensors used in the bladder management system.

FIG. **5** shows a schematic drawing of a bladder management system used in a male urinary control system.

FIG. **6**A shows a schematic drawing of an embodiment of the catheter portion of the bladder management system of FIG. **1**.

FIG. **6**B shows an enlarged view of a valve portion of the catheter of FIG. **6**A.

FIG. **6**C shows a cross-section view of the valve portion of FIG. **6**B across the line a-b.

FIG. **6**D shows an enlarged view of a retaining portion of the catheter of FIG. **6**A.

FIG. **7**A shows a schematic drawing of an embodiment of an extraction device.

FIG. **7**B shows a schematic drawing of an embodiment of a thruster tip of the extraction device of FIG. **7**A.

FIG. **8**A shows a schematic drawing of an embodiment of an insertion device and the catheter.

FIG. **8**B shows a schematic drawing of an embodiment of a mating lip of the insertion device of FIG. **8**A.

FIG. **9** is a functional block diagram which illustrates the operation of a sample sound sensor system.

DETAILED DESCRIPTION

Disclosed herein are embodiments of systems that can be used for bladder management, specifically bladder management for Neurogenic Bladder in a patient. For example, embodiments of the system can be used to sense metrics that can be used to determine the amount of urine inside a person's, or an animal's, bladders and/or the pressure of urine in the bladder. However, the disclosed systems can be used for fluid flow control and sensing for other bodily organs as well, and the particular bodily organ described is not limiting. Further, the bladder management can be based on, for example, characteristics of the urine such as pH level, quantity, volume, pressure, urine constituents, color, odor, turbidity, density, possible pathogens, etc. Bladder management can also be based on the dimension of the urethra such as circumference or diameter, pressure of urine inside the bladder, so forth and the particular example used for bladder management are not limiting. As used herein, the term "user" is intended to include any person trained and able to perform the procedure, including the patient, doctor, caregiver, nurse, etc. The term "patient" and "individual" are intended to be interchangeable. The term "body" used herein is defined as "an animate body" including human, animal, and the like.

Bladder Management System

FIG. **1** shows a generalized schematic drawing of a sample bladder management system. A bladder management system **100** can comprise a body. The body can be a long-term use catheter **105**. The catheter **105** can be shaped and sized to be introduced into the bladder **110** of a patient. The catheter **105** can be fully-internal to the body of the patient. The catheter **105** can comprise a sensor **115** and a valve **120**. The catheter **105** can further comprise a processor **125** and a power source **130**. In some embodiments, the bladder management system **100** can comprise a computing device **135**, and the processor **125** can be configured to communicate with the computing device **135**. For example, the processor **125** can communicate with the computing device using wireless transmission **140**. The computing device **135** can be a mobile phone. In some embodiments, the bladder management system **100** can comprise an external powering system **145**. The external powering system **145** can be configured to transmit energy to the catheter **105**. For example, the power source **130** can be a battery or capacitor, and the external powering system **145** can charge the power source **130** through inductive or wireless means. The external powering system **145** may also utilize energy in other bands of the spectrum (SONAR, Acoustic, Ultrasound, RF, etc) to transmit data that the external unit can sense to extrapolate information about the condition, volume, pressure, or other characteristics of urine in the bladder and also overall bladder health.

The sensor **115** can be used to measure the level of urine **155** in the bladder **110**. The sensor **115** can be placed along the body of the catheter **105**. The sensor **115** can be inductively and capacitively coupled to the processor **125**. The processor **125** can be configured to receive an input from the sensor **115** and produce an output that can be used for bladder management. For example, the processor **125** can receive data from the sensor **115**, and the output from the processor **125** can be used to alert the user about the characteristics of urine and bladder. This external system may also be used to open or close the valve **120**. The valve **120** can be in a fluid communication with the catheter **105**. The valve **120** can be configured to restrict or allow flow of fluid from within the bladder **110**. For example, the valve **120** can be positioned within a portion of the catheter **105** along the urethra. The power source **130** can be inductively and capacitively coupled with the processor **125** and/or the external powering system **145**. The power source **130** can also be coupled with the valve **120**. The power source **130** can be used, for example, to supply the processor with the power to send or receive information from the computing device **135**. The power source **130** can be coupled with the valve **120** and be used to supply the power required to open or close the valve **120**. The external powering system **145** can be connected to an AC outlet and/or utilize DC current from other sources.

The power source **130** can be rechargeable. The power source **130** can be configured to last for an approximate 1-36 months of usage. In some embodiments, the power source **130** is a battery that can be configured to receive an electric charge from an external powering system **145** via wireless recharging technology similar to what is currently available in other devices as Commercial Off The Shelf (COTS) application for wireless induction charging.

The external powering system **145** can comprise a charging pod. The charging pod can be plugged into an alternating current (AC) outlet. When placed in the proscribed location, such as on the front of the abdomen, the power source **130** in the catheter **105** can recharge through magnetic induction technology, for example.

In some embodiments, the computing device **135** can have a software which can be used to interpret the values sent from the sensor **115**. In some embodiments, the sensor **115** is a pressure sensor and the computing device **135** can be used to alert a user about when their bladder is likely to contract and void. In some embodiments, the urine **155** amounts inside the bladder can be calibrated by feedback from the individual user after insertion or implantation. In some embodiments, the sensor can use other spectrums of energy, to include acoustics, to determine the fullness or volume of urine in the bladder. Different types of sensors can be embedded on the catheter to determine important metrics of bladder health including pH, volume, pressure, etc. In some embodiments, this can be accomplished through software that analyzes the sensor **115** response and utilizes machine learning algorithms to predict and interpret this data.

The sensor **115** device can utilize basic wireless transmission protocol to wirelessly send data to a computing device **135** with the control software on it. This can be accomplished in a manner similar to Bluetooth, 802.11 WiFi, SONAR, UltraSound, MedRadio or other wireless communications protocols.

In one embodiment, the sensor **115** can determine the pressure of urine **155** within the bladder **110** and send a signal to the processor **125**. The processor **125** sends information on pressure level in the bladder **110** to the computing device **135**. The computing device **135**, using a software, determines whether urine **155** needs to be drained from the bladder **110**. The computing device **135** will also notify the user to drain urine from the bladder. The user can actuate the valve **120** which will allow urine **155** to leave the bladder **110**. In some embodiments, the sensor **115** can be used to determine when urine has been sufficiently drained from the bladder **110**, such as by determining that the pressure level within the bladder **110** has dropped below a certain level. This information can be used to close the valve **120** and halt the flow of urine **155** from leaving the bladder **110**. This sensing technology is not limited to pressure, and in some embodiments, other metrics can be used to make decisions with clinical impact.

The catheter **105** can be used to determine various conditions within the bladder **110**. The sensor **115** can be a pH sensor, an ultrasonic sensor, a displacement sensor, acoustic sensor, etc. Different types and combinations of sensors can be used. For example, the catheter **105** can comprise a pH sensor and a pressure sensor.

The valve **120** can be configured to increase or decrease the flow rate of urine. For example, the valve can have varying degree of valve opening. The valve **120** opening can be configured to dilate and/or expand in order to increase the volumetric flow rate of urine leaving the bladder **110**. For example, a pin valve can be used. This valve **120** can also be configured to be actuated by the pressure of urine **155** in the bladder **110**.

As shown in FIG. **2**, a bladder management system **200** can comprise a signal-generating sensor **205**. In some embodiments, the bladder management system **200** can comprise a valve **210**, an external actuator **230**, the signal-generating sensor **205** within a catheter **215**, and an external computing device **240**. The signal generating sensor **205** can be an LC resonant sensor, an RFID device, or a speaker. In some embodiments, the system **200** can further comprise a microphone and/or an amplifier. The valve **210** can be configured to open and close using an external valve actuator **230**. The external computing device **240** can be used to send and receive signals **225** to and from the signal-generating sensor **205**. In some embodiments, the external computing device **240** can be programmed to interpret the signal **225** to indicate condition within a patient's bladder **220**.

The user can use the external computing device **240** to generate a signal **225**. The sensor **205** can receive the signal **225** from the external computing device **240** and generate a return signal **225** that can be analyzed and interpreted to determine metrics about the condition of the bladder and/or urine within the bladder (e.g. volume, pressure, pH level, etc.). The computing device **240** can display the desired information to the user or can be cataloged for further review and analysis. In some embodiments, this data may be used to send an alert or notify the user or caregiver based on either pre-determined settings or through machine learning algorithms and/or advanced data analysis techniques. For example, the computing device **240** can receive signal from the sensor **205** that can be interpreted to determine the volume of urine **235** in the bladder **220**. Another example, an algorithm can be used to determine the pressure within the bladder **220** based on relationships with the volume of the bladder **220**. Based on the information available or the notification provided, the user can manually open the valve **210** using the external actuator **230**.

The sensor **205** can be configured to change its mechanical properties (e.g. color, size, shape, etc.) based on pressure changes inside the bladder **220**. The user can use an external device to detect changes in mechanical properties of the sensor **205** by, for example, sending and/or receiving sound waves, light waves, etc. In some embodiments, the internal sensor **205** can function without a power source. By constructing the sensor **205** in a specific manner the external unit can observe changes in the resonant frequency characteristics.

The catheter **215** can comprise a computing device **240**. For example, a computing device **240** can be coupled with the sensor **205** and use a software algorithm to determine urine **235** amount inside the bladder **220** based on data read from the sensor **205**. The user can use an external device that can exchange information with the computing device **240** coupled with the sensor **205**. In some embodiments, the computing device **240** can be linked to an external database. For example, an external database having patient data can be used with the computing device **240** to monitor the patient condition and manage bladder **220** by using data that has been collected and aggregated from other patients and sources. A database can catalog the dataset that will allow for analysis and algorithm development to improve accuracy and support predictive analytics.

Sensor

As schematically shown in FIGS. **3** and **4**, sample embodiments of the device can comprise a catheter **300**, **400** having a proximal end **305**, **405**. The catheter **300**, **400** can comprise a lumen **310**, **410** having a retaining portion **315**, **415** near the proximal end **305**, **405**. The catheter **300**, **400** can house a sensor **320**, **420**. As shown in FIG. **4**, the sensor **420** can comprise a radio unit **425**. For example, the radio unit **425** can be a transceiver. In some embodiments, the radio unit **425** can comprise a microphone. The radio unit **425** can be wirelessly coupled to the sensor **420** via different means, including inductive-capacitive coupling or energy transmission in other mediums such as SONAR, Ultra-Sound, Microwave, etc.

The retaining portion **315**, **415** can be configured to transition from an expanded configuration as shown in FIGS. **3-4** to a collapsed configuration shown in FIG. **8**A. The retaining portion **315**, **415** can be a malecot anchor having a plurality of wings. In the expanded configuration, the retaining portion **315**, **415** can retain and anchor the catheter **300**, **400** within the bladder. In the collapsed configuration, the catheter can be received within and passed through the bladder neck and urethra without causing trauma to the urethra or significant modification to the human anatomy.

The catheter **300**, **400** which includes the sensor **320**, **420** can perform one or more of the following: measure important metrics of urine and the bladder; wirelessly relay this data to an external device; allow a mechanical valve to open upon user input; be semi-permanent, e.g. allowing long-term use and/or extended wear; be inserted via minimally invasive means; utilize wireless recharging or powering technology for the sensor **320**, **420** or power storage unit; and be removed when the user wishes to remove the catheter.

Catheter

As shown in FIG. **5**, the catheter **500** can be fully-internal, meaning the catheter **500** is not visible to the naked eye from the exterior, once the catheter **500** is inside the patient's body. The fully-internal catheter **500** can comprise a proximal portion **505** and a distal portion **510**. The proximal portion **505** can comprise a retaining portion **515** and a sensor **520**. The catheter **500** can comprise a lumen **525**. The distal portion **510** can comprise a valve **530**.

The sensor **520** can be placed proximal to the retaining portion **515**. The sensor **520** can be configured to communicate with an external computing device **535**. In some embodiments the computing device **535** is a mobile phone. In some embodiments, the external computing device **535** may be a transceiver that is able to receive and relay these signals to other devices. The valve **530** can comprise a mating structure **540**. The mating structure **540** can be configured to mate with a corresponding structure of a catheter insertion device and/or that of an extraction device.

In some embodiments, the urine in the bladder **550** can be voided when the user utilizes an external actuator **545** to open the valve **530** and allows the urine to travel through the urethra **560**. This signal can be controlled by the user through the use of an external computing device **535**. In some embodiments, the valve **530** can comprise a magnetic ball valve, and the external actuator **545** car, comprise a magnet. In other embodiments, this external actuator **545** can be a combination of electronic control that may utilize an electromagnet to open the valve **530**. As shown in FIG. **5**, a user can place the external actuator **545** near the valve **530**, e.g. on the skin of patient between the scrotum and the shaft of the penis, to open the valve **530**. The valve **530** can be closed when the actuator **545** is away from the location of the valve **530** inside the patient's body. For example, the valve **530** can be closed when the actuator is inside a patient's side pocket.

The catheter **500** can be constructed in a shape and of a material that is conducive to entry utilizing a medical device, such as an insertion device **700** shown in FIGS. **7**A and **7**B, that will enter through the urinary tract. For example, the catheter **500** may be constructed of a material similar to other existing intermittent catheters on the market (such as PVC, Latex, Silicone, Polyurethane or any blend of these materials). In some embodiments, once inside the bladder **550**, the catheter **500** can comprise a retaining portion **515** that can fix the catheter **500** to the wall of the bladder **550**.

In some embodiments, the sensor **520** can be placed distal to the retaining portion **515**. For example, the sensor **520** can be coupled to the valve **530**. In some embodiments, the valve **530** can comprise an internal actuator. For example, the valve **530** can be configured such that an external computing device **535** can be used to open or close the valve **530** using a signal. In some embodiments, a valve **530** can be placed in the proximal portion **505** of the catheter. For example, the valve **530** can be placed on the neck of the bladder **550**. In some embodiments, the catheter **500** can comprise a retaining portion **515** along a midsection or distal end of the body. For example, the catheter **500** can be configured such that the retaining portion **515** is placed on or near the prostate **555** or along the urethra **560** of the patient, instead of within the bladder **550** of the patient as shown. In some embodiments, this mechanism may be used in combination with the malecot anchor.

Valve

FIGS. **6**A to **6**D are detailed schematic drawings of the catheter **600** using a ball valve **605**. As shown in FIG. **5**A, the catheter **600** comprises an elongated midsection **610** between the proximal portion **615** and the distal portion **620**. The elongated midsection **610** can comprise a flexible tube having a lumen. As shown in FIG. **6**B, the valve **605** can be a cylindrical magnetic ball valve comprising a spring **625**, a spring stabilizer **630**, a magnetic ball **635**, a distal seat **640**, a proximal seat **645**, and a mating structure **655**. The proximal portion **615** can comprise a straight tip. In some embodiments, the proximal portion **615** comprises a coude tip.

The spring **625** can be coupled to the distal seat **640** and configured to constantly exert tension during opening and closing of the valve **605**. The spring stabilizer **630** can be concentric to the center of the valve **605**. The proximal seat **645** can be configured to trap the ball **635** (e.g. by having a ring shape with an inner radius smaller than the radius of the ball **635**). The retainer **650** can be positioned distal and adjacent to the proximal seat **645**. As shown in FIG. **6**C, the distal seat **640** and the proximal seat **645** can comprise one or more inlets **660**. The inlet **660** can be shaped and sized to pass a pushwire **715** shown and described below in reference to FIGS. **7**A and **7**B. As shown in FIG. **6**D, the proximal portion **615** can comprise a fluid inlet **660**. The proximal portion **615** can house a sensor. The mating structure **655** can comprise a tapered surface **665** and a ledge **670**. The mating structure **655** can be configured to expand when thrusting a rigid corresponding structure, e.g. the thruster tip **825** of the extraction device **800** shown in FIG. **8**. The mating structure **655** can comprise a magnetic material. In some embodiments, the mating structure **655** can comprise a conductive material that can be used to complete an external circuit and inform a user that the extraction device **800** is mated to the mating structure **830**.

In some embodiments, the valve **605** can comprise a disc, plug, diaphragm, pinch, check, plunger, flap, duckbill, or other valve designed to actuate upon user input and/or at a calculated pressure threshold. In some embodiments, the valve **605** can comprise a manual squeeze valve (not shown) configured to manually open and close. The manual squeeze valve can comprise an elastic body in a closed state without manual adjustment. When the catheter **600** is inside the patient, the user may squeeze the valve **605** from the skin of the patient to open the valve **605**. From squeezing the valve **605**, the fluid inside the bladder can be drained.

User Insertion and Removal

A fully-internal catheter **600** can be used for extended periods and long-term use rather than requiring intermittent replacement as some existing catheter devices require. The long-term use of a fully-internal catheter **600** can aid in patient comfort, prevent and/or reduce psychological trauma from frequent replacement, reduce occurrence of urinary tract infections, etc. The catheter **600** device can be long-term use because it can be inserted and/or removed by utilizing medical devices, e.g. an insertion device **700**, an extraction device **800**, etc. The removal of the long-term use catheter **600** device can be in a similar manner as when the long-term use catheter **600** device is implanted within the patient. The insertion device **700** and the extraction device **800** can comprise structures corresponding to the mating structure **655** of the valve **605**. The device has been designed in such a way that insertion and extraction can be completed by the user.

Insertion

As shown in FIG. **7**A, the insertion device **700** can comprise a container **705**, an insertion rod **710**, a pushwire **715**, a trigger **735**, and one or more pull strings **725**. The pushwire **715** can be a mandrel. As schematically shown in FIG. 7B, the insertion rod **710** further comprises a lip **720** connected to the one or more pull strings **725**. The lip **720** can be configured to mate with the valve mating structure **830**. For example, as shown in FIG. 7B, the lip **720** can comprise a bottleneck structure that mates with the ledge **845** of the mating structure **830**. When prepared for insertion, the insertion device **700** will translate force along the axis of travel through the urethra **745** until the user chooses to disengage the mating mechanism. The lip **720** can be semi-rigid and have a stiffness sufficient to remain attached to the valve **755** mating structure **830** until disengaged by the user.

The container **705** can be in fluid communication with the rod **710**. The container **705** can be configured to allow visual confirmation of material inside the container **705**. For example, the container **705** can comprise a translucent material, such as translucent PVC. The rod **710** can comprise a hollow tube made of a medical grade material, such as nylon. The pushwire **715** can pass through the hollow tube of the rod **710** and the catheter **740** lumen and comprises a shape memory material used in similar medical applications. For example, the pushwire **715** can comprise a Teflon®-coated nitinol or stainless steel wire having a stiffness to allow bending and flexing without causing trauma to the urethra **745** while the catheter **740** is inserted inside the patient's body. The pushwire **715** can have a longitudinal length longer than the combined longitudinal length of the catheter **740** and the rod **710**. As shown in FIG. 7A, the pushwire **715** has a length such that a portion of the pushwire **715** extends into the container **705**, while the pushwire **715** extends fully along the erect length of the catheter **740** and the rod **710**. During insertion, the pushwire **715** contacts the catheter tip **760** such that thrusting force from the pushwire **715** transports the catheter **740** along the urethra and to the bladder. In some embodiments, the trigger **735** can comprise a ring shape having a dimension to fit a human index finger. The trigger **735** can be connected to the pull string **725** which extends from the lip **720** and through an opening on the rod **710**.

The insertion device **700** and the catheter **740** can be carried in a sterilized pouch. In some embodiments, the insertion device **700** and the catheter **740** can be in a mated state before use. In the mated state, the pushwire **715** extends through the valve **755** such that the valve **755** remains open to allow fluid flow. As shown in FIG. 7A, the retaining portion **750** of the catheter **740** can be folded in the mated state. A user may open the pouch comprising a catheter **740** and the insertion device **700** and insert the catheter **740** into the urethra. The user may move the catheter **740** by moving the catheter **740** proximally using the insertion device **700**. Once the retaining portion **750** reaches the bladder, the retaining portion **750** can expand as the user removes the pushwire **715** and allows the anchor to return to its resting state. The fluid within the bladder may drain from an opening **730** of the retaining portion **750** through the open valve **755**, to the rod **710**, and eventually to the container **705**. The user may observe presence of fluid inside the container **705** to visually confirm placement of catheter **740** and that the catheter **740** has successfully reached the bladder. The user can then remove the pushwire **715** and allow the anchor to expand. The user can actuate the trigger **735** to collapse the lip **720** to disconnect the insertion device **700** from the catheter **740**. The removal of the insertion device **700** can be done subsequent to visual confirmation of the placement of catheter **740**. The user can move the insertion device **700** away from the catheter **740** while the catheter **740** remains within the patient's body.

In some embodiments, fluid flow through the valve **755** can be prevented before and after the insertion of the catheter **740**. For example, the valve **755** can comprise an orifice completely sealed off by the pushwire **715** to prevent fluid flow. In some embodiments, the catheter **740** can comprise a sensor which can notify the user of fluid flow in the catheter **740** upon placing the retaining portion **750** inside the bladder.

Extraction Device

As shown in FIG. **8**A, the extraction device **800** can comprise a handle **805**, an extraction rod **810**, a click button **815**, and a visual indicator **820**. The extraction rod **810** can comprise a cannula. As shown in FIG. **8**B, the extraction device **800** can comprise a thruster **835** inside the extraction rod **810**. The thruster **835** can comprise an extraction tip **825**. The extraction tip **825** can be configured to mate with the mating structure **830** of the valve **755**. For example, the extraction tip **825** can comprise a semi-rigid surface **860** that can be pushed past the tapered surface **855**, and one or more latching wings **840** that can latch onto the ledge **850**. The extraction tip **825** can comprise a magnetic material. In some embodiments, the extraction tip **825** can comprise a conducting material. The click button **815** can be located on the distal tip of the handle **805** opposite the extraction rod **810**. The visual indicator **820** can be an LED light configured to actuator on or off when the extraction tip **825** abuts the valve mating structure **830**. The visual indicator **820** can be located on the handle **805**

The handle **805** can comprise an ergonomic structure and can house a spring. The click button **815** can be used to operate the thruster **835** from a protruding position and retracting position, having mechanics similar to a conventional retractable pen. The extraction device **800** can provide auditory and tactile notice to the user, such as when the click button is pressed, the button "clicks" to indicate that the thruster **835** position has changed. In some embodiments, the handle **805** and the extraction rod **810** can house electronic circuitry connected to the visual indicator. The electronic circuitry connected to the visual indicator **820** can remain broken until the conductive thruster tip **825** connected to the circuitry contacts the valve mating structure **830** to complete the circuitry. For example, the valve mating structure **830** can comprise an annular conductive surface, while the extraction tip **825** can comprise two or more disconnected probe ends configured to contact the annular conductive surface.

The extraction rod **810** of the extraction device **800** can be inserted in the urethra of a patient wearing the fully-internal catheter. The user can determine placement of the extraction tip **825** to the valve mating structure **830** by seeing the visual indicator light turn on. The extraction tip **825** and the valve mating structure **830** can magnetically attach. The user may push the click button **815** to push the latching wing **840** of the thruster tip **825** past the ledge **850**. The thruster tip **825** can flex and collapse to push through the tapered surface **855** and contract to its original shape as the latching wing **840** moves past the ledge **850** to latch onto the ledge **850**. The user may move the extraction device **800** to extract the catheter out of the patient's body and dispose the extraction device **800** and the catheter.

In some embodiments, the visual indicator **820** can remain on until the thruster tip **825** contacts the valve mating structure **830**. In some embodiments, the visual indicator **820** can be located on the click button **815**. Various different types of actuation mechanism can be used. For example, the thruster **835** can be actuated using a turn knob or a screw. In some embodiments, the click button **815** can be located on the side of the handle **805**.

FIG. **9** is a functional block diagram which illustrates the operation of a sample sound sensor system.

Among the many advantages of this invention include increasing the quality of life for individuals suffering from neurogenic bladder by: 1. reducing the risk of medical issues (urinary tract infections, false passage, etc.); 2. eliminating the need for indwelling or intermittent catheters and decreasing the number of catheters required for daily use (because of increased accuracy with which the user knows when catheterization is required); 3. allowing the user to control bladder voiding; 4. accommodating implanted, semi-permanent (useful life 3-6 months) device via minimally invasive means (via catheter); 5. minimizing problems from incontinence and related psychological impact (emotional trauma from accidental urinary voiding); and 6. transmits wireless report data similar to that done in urodynamic flow testing (pressure of bladder at different levels of fullness) more accurately and less invasively.

Although embodiments of the invention have been shown and described, it is to be understood that various modifications, substitutions, rearrangements and different parts, components, equipment, elements and/or process (method) steps, as well as other uses, of the wireless pressure sensor and valve for bladder can be made by those skilled in the art without departing from the novel spirit and scope of this invention.

While several embodiments of the present disclosure have been described and illustrated herein, those of ordinary skill in the art will readily envision a variety of other means and/or structures for performing the functions and/or obtaining the results and/or one or more of the advantages described herein, and each of such variations and/or modifications is deemed to be within the scope of the present disclosure. More generally, those skilled in the art will readily appreciate that all parameters, dimensions, materials, and configurations described herein are meant to be exemplary and that the actual parameters, dimensions, materials, and/or configurations will depend upon the specific application or applications for which the teachings of the present disclosure is/are used.

As used in any embodiment herein, the term "module" may refer to software, firmware and/or circuitry configured to perform any of the aforementioned operations. Software may be embodied as a software package, code, instructions, instruction sets and/or data recorded on non-transitory computer readable storage medium. Firmware may be embodied as code, instructions or instruction sets and/or data that are hard-coded (e.g., nonvolatile) in memory devices. "Circuitry", as used in any embodiment herein, may comprise, for example, singly or in any combination, hardwired circuitry, programmable circuitry such as computer processors comprising one or more individual instruction processing cores, state machine circuitry, and/or firmware that stores instructions executed by programmable circuitry. The modules may, collectively or individually, be embodied as circuitry that forms part of a larger system, for example, an integrated circuit (IC), system on-chip (SoC), desktop computers, laptop computers, tablet computers, servers, smart phones, etc.

Any of the operations described herein may be implemented in a system that includes one or more storage mediums having stored thereon, individually or in combination, instructions that when executed by one or more processors perform the methods. Here, the processor may include, for example, a server CPU, a mobile device CPU, and/or other programmable circuitry.

Unless otherwise indicated, all numbers expressing quantities of ingredients, properties such as molecular weight, reaction conditions, and so forth used in the specification and claims are to be understood as being modified in all instances by the term "about." Accordingly, unless indicated to the contrary, the numerical parameters set forth in the specification and attached claims are approximations that may vary depending upon the desired properties sought to be obtained by the present invention. At the very least, and not as an attempt to limit the application of the doctrine of equivalents to the scope of the claims, each numerical parameter should at least be construed in light of the number of reported significant digits and by applying ordinary rounding techniques. Notwithstanding that the numerical ranges and parameters setting forth the broad scope of the invention are approximations, the numerical values set forth in the specific examples are reported as precisely as possible. Any numerical value, however, inherently contains certain errors necessarily resulting from the standard deviation found in their respective testing measurements.

The terms "a," "an," "the" and similar referents used in the context of describing the invention (especially in the context of the following claims) are to be construed to cover both the singular and the plural, unless otherwise indicated herein or clearly contradicted by context. Recitation of ranges of values herein is merely intended to serve as a shorthand method of referring individually to each separate value falling within the range. Unless otherwise indicated herein, each individual value is incorporated into the specification as if it were individually recited herein. All methods described herein can be performed in any suitable order unless otherwise indicated herein or otherwise clearly contradicted by context. The use of any and all examples, or exemplary language (e.g., "such as") provided herein is intended merely to better illuminate the invention and does not pose a limitation on the scope of the invention otherwise claimed. No language in the specification should be construed as indicating any non-claimed element essential to the practice of the invention.

Certain embodiments of this invention are described herein, including the best mode known to the inventors for carrying out the invention. Of course, variations on these described embodiments will become apparent to those of ordinary skill in the art upon reading the foregoing description. The inventor expects skilled artisans to employ such variations as appropriate, and the inventors intend for the invention to be practiced otherwise than specifically described herein Accordingly, this invention includes all modifications and equivalents of the subject matter recited in the claims appended hereto as permitted by applicable law. Moreover, any combination of the above-described elements in all possible variations thereof is encompassed by the invention unless otherwise indicated herein or otherwise clearly contradicted by context.

Specific embodiments disclosed herein may be further limited in the claims using consisting of or consisting essentially of language. When used in the claims, whether as filed or added per amendment, the transition term "consisting of excludes any element, step, or ingredient not specified in the claims. The transition term "consisting essentially of" limits the scope of a claim to the specified materials or steps and those that do not materially affect the basic and novel characteristic(s). Embodiments of the invention so claimed are inherently or expressly described and enabled herein.

Furthermore, numerous references have been made to patents and printed publications throughout this specification. Each of the above-cited references and printed publications are individually incorporated herein by reference in their entirety.

In closing, it is to be understood that the embodiments of the invention disclosed herein are illustrative of the principles of the present invention. Other modifications that may be employed are within the scope of the invention. Thus, by way of example, but not of limitation, alternative configurations of the present invention may be utilized in accordance with the teachings herein. Accordingly, the present invention is not limited to that precisely as shown and described.

Unless otherwise indicated, all numbers expressing quantities of ingredients, properties such as molecular weight, reaction conditions, and so forth used in the specification and claims are to be understood as being modified in all instances by the term "about." Accordingly, unless indicated to the contrary the numerical parameters set forth in the specification and attached claims are approximations that may vary depending upon the desired properties sought to be obtained by the present invention. At the very least, and not as an attempt to limit the application of the doctrine of equivalents to the scope of the claims, each numerical parameter should at least be construed in light of the number of reported significant digits and by applying ordinary rounding techniques. Notwithstanding that the numerical ranges and parameters setting forth the broad scope of the invention are approximations, the numerical values set forth in the specific examples are reported as precisely as possible. Any numerical value, however, inherently contains certain errors necessarily resulting from the standard deviation found in their respective testing measurements.

The terms "a," "an," "the" and similar referents used in the context of describing the invention (especially in the context of the following claims) are to be construed to cover both the singular and the plural, unless otherwise indicated herein or clearly contradicted by context. Recitation of ranges of values herein is merely intended to serve as a shorthand method of referring individually to each separate value falling within the range. Unless otherwise indicated herein, each individual value is incorporated into the specification as if it were individually recited herein. All methods described herein can be performed in any suitable order unless otherwise indicated herein or otherwise clearly contradicted by context. The use of any and all examples, or exemplary language (e.g., "such as") provided herein is intended merely to better illuminate the invention and does not pose a limitation on the scope of the invention otherwise claimed. No language in the specification should be construed as indicating any non-claimed element essential to the practice of the invention.

Groupings of alternative elements or embodiments of the invention disclosed herein are not to be construed as limitations. Each group member may be referred to and claimed individually or in any combination with other members of the group or other elements found herein. It is anticipated that one or more members of a group may be included in, or deleted from, a group for reasons of convenience and/or patentability. When any such inclusion or deletion occurs, the specification is deemed to contain the group as modified thus fulfilling the written description of all Markush groups used in the appended claims.

Certain embodiments of this invention are described herein, including the best mode known to the inventors for carrying out the invention. Of course, variations on these described embodiments will become apparent to those of ordinary skill in the art upon reading the foregoing description. The inventor expects skilled artisans to employ such variations as appropriate, and the inventors intend for the invention to be practiced otherwise than specifically described herein. Accordingly, this invention includes all modifications and equivalents of the subject matter recited in the claims appended hereto as permitted by applicable law. Moreover, any combination of the above-described elements in all possible variations thereof is encompassed by the invention unless otherwise indicated herein or otherwise clearly contradicted by context.

Specific embodiments disclosed herein may be further limited in the claims using consisting of or consisting essentially of language. When used in the claims, whether as filed or added per amendment, the transition term "consisting of" excludes any element, step, or ingredient not specified in the claims. The transition term "consisting essentially of" limits the scope of a claim to the specified materials or steps and those that do not materially affect the basic and novel characteristic(s). Embodiments of the invention so claimed are inherently or expressly described and enabled herein.

As one skilled in the art would recognize as necessary or best-suited for performance of the methods of the invention, a computer system or machines of the invention include one or more processors (e.g., a central processing unit (CPU) a graphics processing unit (GPU) or both), a main memory and a static memory, which communicate with each other via a bus.

A processor may be provided by one or more processors including, for example, one or more of a single core or multi-core processor (e.g., AMD Phenom II X2, Intel Core Duo, AMD Phenom II X4, Intel Core i5. Intel Core I & Extreme Edition 980X, or Intel Xeon E7-2820).

An I/O mechanism may include a video display unit (e.g., a liquid crystal display (LCD) or a cathode ray tube (CRT)), an alphanumeric input device (e.g., a keyboard), a cursor control device (e.g., a mouse), a disk drive unit, a signal generation device (e.g., a speaker), an accelerometer, a microphone, a cellular radio frequency antenna, and a network interface device (e.g., a network interface card (N IC), Wi-Fi card, cellular modem, data jack, Ethernet port, modem jack, HDMI port, mini-HDMI port, USB port), touchscreen (e.g., CRT, LCD, LED, AMOLED, Super AMOLED), pointing device, trackpad, light (e.g., LED), light/image projection device, or a combination thereof.

Memory according to the invention refers to a non-transitory memory which is provided by one or more tangible devices which preferably include one or more machine-readable medium on which is stored one or more sets of instructions (e.g., software) embodying any one or more of the methodologies or functions described herein. The software may also reside, completely or at least partially, within the main memory, processor, or both during execution thereof by a computer within system, the main memory and the processor also constituting machine-readable media. The software may further be transmitted or received over a network via the network interface device.

While the machine-readable medium can in an exemplary embodiment be a single medium, the term "machine-readable medium" should be taken to include a single medium or multiple media (e.g., a centralized or distributed database, and/or associated caches and servers) that store the one or more sets of instructions. The term "machine-readable medium" shall also be taken to include any medium that is capable of storing, encoding or carrying a set of instructions for execution by the machine and that cause the machine to perform any one or more of the methodologies of the present invention. Memory may be, for example, one or more of a hard disk drive, solid state drive (SSD), an optical disc, flash memory, zip disk, tape drive, "cloud" storage location, or a combination thereof. In certain embodiments, a device of the invention includes a tangible, non-transitory computer readable medium for memory. Exemplary devices for use as memory include semiconductor memory devices, (e.g., EPROM, EEPROM, solid state drive (SSD), and flash memory devices e.g., SD, micro SD, SDXC, SDIO, SDHC cards); magnetic disks, (e.g., internal hard disks or removable disks); and optical disks (e.g., CD and DVD disks).

Furthermore, numerous references have been made to patents and printed publications throughout this specification. Each of the above-cited references and printed publications are individually incorporated herein by reference in their entirety.

In closing, it is to be understood that the embodiments of the invention disclosed herein are illustrative of the principles of the present invention. Other modifications that may be employed are within the scope of the invention. Thus, by way of example, but not of limitation, alternative configurations of the present invention may be utilized in accordance with the teachings herein. Accordingly, the present invention is not limited to that precisely as shown and described.

What is claimed is:

1. A bladder management system comprising a fully-internal catheter and devices for transporting the fully-internal catheter within a body of a patient, the system comprising:

the fully-internal catheter configured to be placed inside a bladder of a patient's body and invisible to human eyes from outside of the body once inside the bladder, the fully internal catheter comprising a first mating structure; and

one or more transporting devices comprising a second mating structure configured to mate with the first mating structure, an insertion device and an extraction device, wherein the insertion device comprises the second mating structure and the extraction device comprises a third mating structure configured to mate with the first mating structure, and wherein the insertion device comprises the second mating structure comprising a semi-rigid lip and one or more pull strings connected to the semi-rigid lip.

2. The system of claim **1**, wherein the fully-internal catheter comprises a proximal end and a distal end, the proximal end comprising an opening and the distal end comprising the first mating structure.

3. The system of claim **2**, wherein the proximal end comprises a retaining portion configured to be deployed when the retaining portion is placed in the bladder.

4. The system of claim **1**, wherein the first mating structure comprises a tapered surface and a latching tip.

5. The system of claim **1**, wherein the first mating structure comprises a first configuration and a second configuration, wherein the first mating structure expands in the first configuration and returns to its original shape and mates with the second mating structure in the second configuration.

6. The system of claim **1**, wherein the second mating structure comprises a first configuration and a second configuration, wherein the second mating structure is mated to the first mating structure in the first configuration and can be removed from the first mating structure in the second configuration.

7. The system of claim **1**, wherein the fully-internal catheter comprises a valve, and the first mating structure comprises a valve mating tip.

8. The system of claim **1**, wherein a pulling force transmitted through the one or more pull strings to the semi-rigid lip deforms and releases the semi-rigid lip from the first mating portion.

9. The system of claim **1**, wherein the extraction device comprises a thruster and the third mating structure comprises a thrusting tip connected to the thruster.

10. The system of claim **9**, wherein the thrusting tip comprises a blunt surface and a latching structure, the blunt surface configured to thrust and expand the first mating structure and the latching structure configured to latch onto a corresponding structure on the first mating structure.

11. The system of claim **10**, wherein the corresponding structure is a ledge.

12. The system of claim **1**, further comprising at least a sensor.

13. The system of claim **1**, further comprising a processor with wireless capability and a battery.

14. The system of claim **1**, further comprising magnetically attached mating structures.

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